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Food and Drug Administration
Atlanta District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

60 8th Street, N.E.
Atlanta, Georgia 30309

November 25, 2002

VIA FEDERAL EXPRESS

CEO/President
Griffon Marketing
Dept. W
384 Green Leaf Drive
Grovetown, GA 30813

WARNING LETTER
(03-ATL-06)

Dear Sir/Madam:

This letter is written in reference to your firm's marketing of "Cyclobol Sublingual Tablets and Tranzabol". These products are labeled to contain androstenediol. Your Internet web site, http://www.drugfreebodybuilding.com, from which these products may be ordered, states, for example, "Cyclobol Sublingual Tablets...increases testosterone levels...muscle repair, rebuild and growth...virility..." and "...Tranzabol...increase testosterone levels...rock-hard gains in muscle size...increased sex drive...".

Tranzabol is topically applied for transdermal absorption to achieve its intended effect. Cyclobol Sublingual Tablets is a sublingual product. These products cannot be dietary supplements because they are not intended for ingestion since they are topical or sublingual products that are intended to bypass the alimentary canal by direct absorption through the skin, or oral mucosa. The Federal Food, Drug and Cosmetic Act (the Act) defines the term, "dietary supplement" in Section 201(ff)(2)(A)(i) to mean product that is "...intended for ingestion..." Consequently, a product that is not intended for ingestion cannot meet the definition of "dietary supplement".

Based on their intended uses, to affect the structure or any function of the body of man, these products are drugs within the meaning of Section 201(g) of the Act. As drugs, the labeling claims made for these products subject them to the requirements for new drugs [Section 201(p) of the Act] because there is no evidence that these products are generally recognized as safe and effective for their claimed uses. Further, all transdermal drug delivery products are new drugs

because of the newness of the dosage or the method or duration of administration or application suggested in the labeling (See Title 21 of the Code of Federal Regulations, Part 310.3). Under Section 505 of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Because your products are not the subject of approved NDA's, they may not be marketed in the United States and their continued distribution violates Section 505 of the Act.

This letter is not intended to be an all-inclusive review of your Internet web site nor all labeling and products your firm markets. The violation described above is not intended to be an all inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm, including other products containing androstenediol, are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be implemented.

Please send your reply to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. If you have questions regarding any issue in the letter, please contact Mr. Campbell at 404-253-1280.

Sincerely,

Barbara A. Wood, Acting Director
Atlanta District